510(K) Summary of Safety & Effectiveness

AUG 28 2008

Submitted By	MEDISISS 2747 SW 6th St. Redmond, OR 97756
Contact Names	Brandi James Director, Technical Services P: 541-923-3310 F: 541-923-3375 E: bjames@medisiss.com
Submission Date	June 2, 2008
Proprietary Device Name	Genesis™
Classification	Electrosurgical Electrodes, Class II, Electrosurgical cutting and coagulation device and accessories, General and plastic surgery (21 CFR 878.4400), GEI
Predicate Devices	Valleylab Uncoated Electrosurgical Blade (E1551X) (Preamendment) Valleylab EDGE™ Coated Electrosurgical Blade (E1450X): K962044 Conmed Coated Electrosurgical Blade (139100) K991855 Megadyne Coated Eelectrosurgical Blade (0012) K913473 Surginetics AdvantageBlade Electrosurgical Blade K062350 Myco Medical Surgical Blades (non-electrosurgical) Exempt
Indications for Use	The Genesis is indicated for use in surgical procedures (general neurosurgical, laparoscopic, orthopedic, gynecologic, etc.) where monopolar electrosurgical cutting and coagulation are normally used. The Genesis instruments are an alternative to conventional monopolar electrosurgical electrodes used for these indications.
Product Description	The Genesis is an instrument intended for use as a monopolar electrosurgical accessory. The device reduces the smoke emitted into the surgical area, uses lower power with less tissue damage and the outer layer provides a surface that reduces tissue accumulations and facilitates removing tissue residues, such as eschar, that may accumulate during use. Genesis devices are intended for use with monopolar electrosurgical accessories and will be packaged separately. Genesis instruments will also fit in currently marketed electrosurgical pencils offered by other manufacturers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 28 2008

MEDISISS
% Ms. Brandi James
Director, Technical Services
2747 SW 6th Street
Redmond, Oregon 97756

Re: K081559
Trade/Device Name: Genesis
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 5, 2008
Received: August 5, 2008

Dear Ms. James:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): Not assigned at this time.

Device Name: Genesis

Indications For Use:

The Genesis is indicated for use in surgical procedures (general neurosurgical, laparoscopic, orthopedic, gynecologic, etc.) where monopolar electrosurgical cutting and coagulation are normally used. The Genesis instruments are an alternative to conventional monopolar electrosurgical electrodes used for these indications.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081559